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SPEAKER BIOGRAPHIES

In order of presentations (see the Agenda)

Janet Woodcock, MD
Acting Commissioner
US Food and Drug Administration (US FDA)

Janet Woodcock was named Acting Commissioner of Food and Drugs on January 20, 2021.

As Acting Commissioner, Dr. Woodcock oversees the full breadth of the FDA portfolio and execution of the Federal Food, Drug, and Cosmetic Act and other applicable laws. This includes assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices; the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation; and the regulation of tobacco products.

Dr. Woodcock began her FDA career in 1986, joining the agency's Center for Biologics Evaluation and Research (CBER) as Director of the Division of Biological Investigational New Drugs, as well as serving as CBER's Acting Deputy Director for a period of time. She later became Director of the Office of Therapeutics Research and Review in CBER, which included the approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis during her tenure.

In 1994, Dr. Woodcock was named Director of the FDA's Center for Drug Evaluation and Research (CDER), overseeing the center's work that is the world's gold standard for drug approval and safety. There she led many of the FDA's drug initiatives, including introducing the concept of risk management as a new approach to drug safety; modernizing drug manufacturing and regulation through the Pharmaceutical Quality for the 21st Century Initiative; advancing medical discoveries from the laboratory to consumers more efficiently under the Critical Path Initiative; and launching the Safety First and Safe Use initiatives designed to improve drug safety management within and outside the FDA, respectively.

In 2004, Dr. Woodcock became Deputy Commissioner and Chief Medical Officer in the Office of the Commissioner. Later she took on other executive leadership positions in the Commissioner's Office, including Deputy Commissioner for Operations and Chief Operating Officer.

In 2007, Dr. Woodcock returned as Director of CDER until she was asked to lend her expertise to "Operation Warp Speed" for developing therapeutics during the COVID-19 pandemic, such as evaluating the potential benefits of monoclonal antibody treatments for certain COVID-19 patients. From late 2020, she split her time advising "Operation Warp Speed" on advancing COVID-19 therapeutics while also serving as the Principal Medical Advisor to the Commissioner on key priorities on behalf of the Office of the Commissioner.

Dr. Woodcock holds a Bachelor of Science in chemistry from Bucknell University (Lewisburg, PA), and a Doctor of Medicine from the Feinberg School of Medicine at Northwestern University Medical School (Chicago). She also completed further training and a fellowship in rheumatology, as well as held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She is board certified in internal medicine.

Dr. Woodcock has been bestowed numerous honors over her distinguished public health career, most notably: A Lifetime Achievement Award in 2015 from the Institute for Safe Medication Practices; the Ellen V. Sigal Advocacy Leadership Award in 2016 from Friends of Cancer Research; the Florence Kelley Consumer Leadership Award in 2017 from the National Consumers League; and the 2019 Biotechnology Heritage Award from the Biotechnology Innovation Organization and Science History Institute.

Michael Kopcha, Ph.D., R.Ph.
Director
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research (CDER) | US FDA

Michael Kopcha, Ph.D., R.Ph. is the Director of the FDA's Office of Pharmaceutical Quality (OPQ). This office has over 1,300 staff responsible for assuring the availability of quality medicines for the American public through assessment, inspection, surveillance, research, and policy. OPQ contributes to the assessment of nearly every type of human drug marketing application including New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologics License Applications (BLAs), including 351(k) applications (i.e., biosimilars). OPQ also performs the quality assessment of Investigational New Drug Applications (INDs) and establishes quality standards for over-the-counter drug products and facilities.

Prior to joining the FDA, Dr. Kopcha amassed more than 25 years of experience in major and mid-sized innovator, generic, drug/device, and over-the counter (OTC) pharmaceutical and consumer health companies. He developed expertise in areas including formulation and process development, product scale-up, process validation, technology transfer, project management, change management, and off-shoring/outsourcing. Dr. Kopcha most recently served as Vice President, and global research and development franchise head, for cough, cold, and respiratory products at Novartis Consumer Health, Inc.

Dr. Kopcha earned his doctorate and master's degrees in pharmaceutical science, and a bachelor's degree in pharmacy from Rutgers University. He also served as an adjunct assistant professor in the Department of Pharmaceutics at Ernest Mario School of Pharmacy at Rutgers.

Lucinda (Cindy) Buhse, Ph.D.
Deputy Director of Operations
OPQ | CDER | US FDA

Dr. Buhse joined FDA in 2001 in OPQ's Office of Testing and Research. She was Director for Office of Testing and Research from 2013 to 2017 and the Director for the Office of Quality Surveillance (OQS) from 2017-2019. Before joining the FDA, Dr. Buhse worked in management positions in Production, Validation and Analytical Services at Sigma Aldrich Corporation and as a Senior Research Scientist for Rohm and Haas Company. Dr. Buhse received a B.A. in Chemistry from Grinnell College and a Ph.D. in Physical Chemistry from the University of California, Berkeley.

Laurie Graham
Director
Division of Internal Policies and Programs (DIPAP)
Office of Policy for Pharmaceutical Quality (OPPQ)
OPQ | CDER | US FDA

Laurie is currently the Director of the Division of Internal Policies and Programs (DIPAP) in the Office of Policy for Pharmaceutical Quality (OPPQ) in the Office of Pharmaceutical Quality (OPQ) at the Center for Drugs Evaluation and Research (CDER). DIPAP is responsible for the development and evaluation of CDER's internal policies and programs related to pharmaceutical quality, including application assessment and inspection.

Prior to joining OPPQ, Laurie had more than 20 years of experience at the FDA. Laurie first joined the FDA in 1993 as a full-time research biologist investigating the response of immune cells to perturbation by physiological ligands or pharmaceutical agents, such as monoclonal antibodies. In 2003, Laurie assumed product quality regulatory assessment responsibilities and became a product quality team leader in 2013. During this time, Laurie's product quality related regulatory responsibilities included inspections and application assessments for monoclonal antibodies, novel antibody products, Fc-fusion proteins, and combination products.

Stelios Tsinontides, Ph.D.
Director
Office of Pharmaceutical Manufacturing Assessment (OPMA)
OPQ | CDER | US FDA

Dr. Stelios Tsinontides is Director of the Office of Pharmaceutical Manufacturing Assessment (OPMA) under the Office of Pharmaceutical Quality (OPQ) in CDER. Dr. Tsinontides has over 25 years of experience in the pharmaceutical industry. OPMA evaluates facilities, process design, and control strategies to assess capabilities of manufacturers to produce quality pharmaceutical and biotechnology products at commercial scale and provides leadership and technical expertise to Agency components internal and external to the Office of Pharmaceutical Quality regarding manufacturing quality issues.
Prior to joining the FDA, Dr. Tsinontides served in senior-level positions in the pharmaceutical industry - most recently as Shire's Head of Small Molecule (SM) Drug Product Technical Services. His group was responsible for providing scientific and technical expertise for SM Drug Product scale-up and commercial manufacturing activities worldwide, to ensure establishment of commercial robust manufacturing processes and a continuous supply of product to patients.
Dr. Tsinontides holds a B.E. in Chemical Engineering from City College of CUNY and an M.A. and Ph.D. in Chemical Engineering from Princeton University. He's also studied in the Wharton Management Program at the University of Pennsylvania. Dr. Tsinontides is also a Fellow at the American Institute of Chemical Engineering (AIChE).

Nancy Rolli
Deputy Director
Office of Pharmaceutical Quality Operations (OPQO)
Office of Regulatory Affairs (ORA) | US FDA

Nancy Rolli is the Deputy Director of the Office of Pharmaceutical Quality Operations, a program within the Office of Regulatory Affairs (ORA), at the Food and Drug Administration (FDA). As the Deputy Director she assists with coordination and management of ORA's field activities and works in close conjunction with FDA's Center for Drug Evaluation and Research (CDER) and the Center for Veterinary Medicine (CVM). Ms. Rolli is involved in many Pharma initiatives; she is the co-chair for the Pre-Approval New Inspection Protocol workgroup and provides training at ORA national training courses.

From 2015 – 2017, Ms. Rolli served as the acting director of the Office of Medical Products and Tobacco Operations with ORA. She was charged with managing and leading a staff in the area of medical products and tobacco operations. She worked closely with other divisions and Centers to leverage inspectional resources and acted as a liaison between the districts and the centers. From 2011 – 2015, Ms. Rolli was the director of FDA's New Jersey District, Investigations Branch where she provided leadership in directing and managing the district's inspectional activities which include inspections of all regulated products. From 2008 - 2011, Ms. Rolli was the director of FDA's New Jersey District Compliance Branch and was responsible for all regulatory actions taken by New Jersey District. Ms. Rolli received her Bachelor of Science Degree from the State University on New York. She has received numerous awards and citations for her public service and she enjoys her role as a public health servant and trainer at the agency's national training courses.

Theresa Mullin, Ph.D.
Associate Director for Strategy
Office of the Center Director (OCD) | CDER | US FDA

Dr. Mullin is the CDER Associate Center Director for Strategic Initiatives. She oversees areas of strategic interest to the Center and external stakeholders, leading a variety of CDER efforts including Patient-Focused Drug Development (PFDD), and the Rare Disease Cures Accelerator. She also leads CDER's International Program, participating in ICMRA, ICH, IPRP and PIC/S, and she leads the FDA delegation to the International Council on Harmonization (ICH) where she also played a lead role in recent reforms, and currently serves as Chair of the ICH Management Committee.

Dr. Mullin previously served as director of CDER's Office of Strategic Program which she established and led for almost a decade. She led FDA negotiations with industry and public consultations to support the 2017 reauthorization of the Prescription Drug User Fee Act (PDUFA) and Biosimilar User Fee Act and led the previous 3 cycles of negotiation for the 2002, 2007 and 2012 reauthorizations of PDUFA, now providing $1B in annual funding. Before joining CDER in 2007, Dr. Mullin was Assistant Commissioner for Planning in FDA's Office of the Commissioner.

Since joining FDA Dr. Mullin has received numerous awards including the 2019 Reagan-Udall Foundation Leadership Award for Innovations in Regulatory Science, the FDA 2019 Innovator Award, US Food and Drug Law Institute 2017 Distinguished Service and Leadership Award, the Presidential Rank Award for Distinguished Service in 2011, Presidential Rank Award for Meritorious Service in 2006. Dr. Mullin received her BA, *magna cum laude*, in Economics from Boston College, and PhD in Public Policy Analysis from Carnegie-Mellon University.

Don Ashley, J.D.
Director
Office of Compliance (OC) | CDER | US FDA

As Director of CDER's Office of Compliance, Donald D. Ashley, J.D., leads efforts to shield the American public from unsafe, ineffective, and low-quality drug products through measures designed to assist industry-wide compliance with federal standards for quality and safety, as well as regulatory and enforcement measures to address violations of those standards.

Mr. Ashley joined FDA after more than 18 years of criminal enforcement and investigation experience with the Department of Justice. His positions included serving as a Trial Attorney in the Office of Consumer Litigation (now the Consumer Protection Branch), prosecuting consumer fraud offenses and violations of the Food Drug and Cosmetic Act, as Associate Director of the Office of International Affairs, and as the DOJ Attaché stationed at the U.S. Embassy in Rome and at the U.S. Embassy in Manila, Philippines.

Before joining DOJ, Mr. Ashley served as senior litigation associate with a major D.C. law firm, representing clients under investigation for FD&C Act violations. He also served on active duty as an Army captain assigned to the Office of General Counsel, Department of the Army. Mr. Ashley was an adjunct professor of law at Georgetown, George Washington, American and Catholic Universities.

Mr. Ashley earned his law degree from Harvard Law School.

Elizabeth Miller, PharmD
Assistant Commissioner
Office of Medical Products and Tobacco Operations (OMPTO)
ORA

Dr. Elizabeth Miller recently rejoined the US FDA in March 2020. In her role as the Assistant Commissioner for Medical Products and Tobacco Operations, Dr. Miller provides leadership and managerial direction to ORA's Office of Biologics Products Operations, Office of Pharmaceutical Quality Operations, Office of Medical Device and Radiological Health Operations, Office of Bioresearch Monitoring Operations, and the Tobacco Operations Staff.

Dr. Miller comes returns from the U.S. Pharmacopeia (USP) where she helped guide USP's working relationship with the FDA. At USP, Dr. Miller was vice president, US Public Policy & Regulatory Affairs, with responsibility to deliver executive leadership for developing and achieving USP's US regulatory science and intelligence, government affairs, and public policy programs' goals. She also created strategic change focused on impacts and results resulting from engagement with federal, state, and international regulators, as well as senior leadership in industry, academia, and patient-focused alliances.

Before rejoining USP in 2016, Dr. Miller began her federal career with FDA's Center for Drug Evaluation and Research (CDER) in 2007 in the Office of Unapproved Drugs and Labeling Compliance (OUDLC). She began her CDER career working on online pharmacy and health fraud issues, and ultimately served as the director for OUDLC's Division of Nonprescription Drugs & Health Fraud.

Prior to federal service, Dr. Miller worked at USP as a scientific liaison on medication safety standards for nomenclature, labelling, and packaging, and as the director of drug information for the USP Drug Information publication. She started her pharmacy career working as a clinical pharmacist at MedStar Washington Hospital Center in Washington D.C.
Dr. Miller holds a bachelor's degree in biology from The Johns Hopkins University and received her Doctor of Pharmacy degree from the University of Maryland.

Don Henry
Director
Office of Program and Regulatory Operations (OPRO)
OPQ | CDER | US FDA

Mr. Henry joined FDA in 2008 as a Regulatory Project Manager in the Office of New Drug Quality Assessment (now part of OPQ) where he managed pre-market and post-market applications. He has also served as a Project Manager to facilitate the Quality by Design (QbD) Program for the office which included leading a QbD assessment pilot with the European Medicine Agency (EMA). Prior to joining the FDA, Mr. Henry gained experienced working in the pharmaceutical industry managing validation and process development and scale-up for companies including AstraZeneca (formerly Zeneca), Biovail Technologies, and Baxter Bioscience. When OPQ was launched, Don served as the Associate Director for Business Operations in OPRO prior to transitioning to the Office Director role. Don has a B.S. degree in mechanical engineering from the University of Delaware.

Ee-Sunn "Joanne" Chia, Ph.D.
Division Director
Division of New Drug Products II (DNDPII)
Office of New Drugs Products (ONDP)
OPQ | CDER | US FDA

Dr. Ee-Sunn (Joanne) Chia is the Director of the Division of New Drug Products III on ONDP. She joined the FDA in 2013 as drug product reviewer.

Joanne earned a B.S. in Chemical Engineering from the University of Virginia and a Ph.D. in Chemical Engineering from Princeton University.

In Joanne's current role as division director, she is shaping culture and helping modernize FDA's regulatory review operations in ONDP via numerous working groups and initiatives. This includes most recently, the KASA for drug substance working group which developed a knowledge aided structured application framework applicable across both generic drug and new drug API assessments.

Joel Welch, PhD
Associate Director for Science
Office of Biotechnology Products (OBP)
OPQ | CDER

Joel Welch is the Associate Director for Science& Biosimilar Strategy in the Office of Biotechnology Products in the Office of Pharmaceutical Quality at the US Food and Drug Administration. He is responsible for assessing emerging, complex, or precedent-setting issues impacting science policies of the office with particular emphasis on the biosimilar program. He also serves as the Rapporteur for the ICH revision to Q5A(R1) and the Vice Chair for the Emerging Technology Program. In his time at FDA, he has also served as a Review Chief, Team Leader, Primary Assessor and Regulatory Project Manager. Prior to joining FDA, he spent 6 years in industry supporting late state analytical development of small molecules.

Alex Viehmann
Division Director
Division of Quality Intelligence II
Office of Quality Surveillance (OQS)
Office of Pharmaceutical Quality (OPQ) | CDER | US FDA

Alex Viehmann is currently the Director for the Division of Quality Intelligence II within the Office of Pharmaceutical Quality/Office of Quality Surveillance. The Division performs post-market quality-based assessments of drug sites and products, enhanced by data integration and analytics tools developed in support of monitoring and improving drug quality, to inform congressional inquiries and data calls, future GMP inspections, enforcement decisions, and application assessment. Alex joined the FDA in May 2008 as an Operations Research Analyst in the Policy and Standards Development staff within the Office of Pharmaceutical Sciences where he collaborated with stakeholders on developing policy and standards on sampling, test method evaluation, and statistical quality control. He then transitioned to the Science and Research staff where he provided statistical support for CMC review, GMP inspections, and enforcement actions. Since joining OQS in 2015, Alex has guided the development of OPQ's Quality Metrics program, CDER/ORA's New Inspection Protocol Project (NIPP), and OQS's analytics and modeling program. He is also actively engaged in implementing Pharmaceutical Quality System (PQS) assessments in support of Established Conditions and the Site Engagement Program (SEP). He currently serves as the Regulatory Chair for ICH Q9 and as a member of the PIC/S Expert Circle Working Group on Quality Risk Management.

Alex received his Bachelor's degree in economics from the University of Maryland at College Park.

Brian Hasselbalch
Deputy Director
OPPQ | OPQ | CDER

Brian Hasselbalch is the Deputy Director, Office of Policy for Pharmaceutical Quality. He began his FDA career 31 years ago inspecting drug manufacturing operations before joining CDER in the Office of Compliance where he handled enforcement actions and related policies before joining OPQ in 2015.

Francis Godwin, MBA
Office Director
Office of Manufacturing Quality (OMQ)
OC | CDER

Francis Godwin received his undergraduate degree from MIT in Chemical Engineering in 2001. After graduation he worked as a process engineer designing, building, and optimizing chemical plants. He was certified as a Black Belt in Six Sigma performing quality improvement projects and teaching Six Sigma principals. He then worked in pharmaceutical process validation for both batch and continuous processes for APIs and finished dosage manufacturing operations. Later, he managed an analytical chemistry laboratory conducting analyses for production, QA, and research testing. In 2009 he received an MBA from Georgetown University and since then, has been working at FDA in CDER's Office of Compliance. He has served in various functions within compliance and is currently the Director of the Office of Manufacturing Quality, overseeing regulatory and enforcement actions for both foreign and domestic drug CGMP cases.

Jennifer Maguire, Ph.D.
Director
OQS |OPQ | CDER

Dr. Jennifer Maguire is the Director of the Office of Quality Surveillance/OPQ/CDER/FDA. The office assesses intelligence throughout the drug product lifecycle to inform stakeholders about the state of pharmaceutical quality and uses data analytics to drive surveillance decisions. During her tenure at the agency, Dr. Maguire has contributed to multiple initiatives aimed at advancing the regulation of pharmaceutical manufacturing and product quality including Question-based Review, Quality by Design, ICH Q12, Site Selection Model Program, Quality Metrics and Quality Management Maturity. Prior to joining the agency in 2010, she worked in industry on the development and scale-up of drug substance manufacturing processes and the manufacturing of drug product clinical and stability supplies. Dr. Maguire has a BS in Chemical Engineering from the University of Virginia and a PhD in Industrial and Physical Pharmacy from Purdue University.

Obinna Ugwu-Oju
Division Director
Division of Quality Data Science (DQDS)
OQS | OPQ | CDER | US FDA

Obinna is currently a Division Director in CDER OPQ Office of surveillance, where he oversees the catalog of CDER regulated manufacturing sites and products and provides oversight to the CDER ORA Site Selection Model (SSM) that is used to prioritize sites for risk-based surveillance inspection. He leads the Integrated Project Team that is tasked with building the CARES Act Drug and Biological Products Amounts Reporting Portal.

Before joining FDA, Obinna worked with Macfadden Associates (now part of PAE) as an enterprise search architect. Obinna earned his B.S. in Electrical Engineering from University of Nigeria, and his M.S. in Telecommunication and Computers from The George Washington University.

DAY 2 Speakers

Jason Rodriguez, Ph.D.
Division Director
Division of Complex Drug Analysis
Office of Testing and Research (OTR)
OPQ | CDER

Jason Rodriguez is the Director for the FDA Division of Complex Drug Analysis in St. Louis, MO. He has a Ph.D. in Chemistry from the University of Illinois Urbana-Champaign and B.S. in chemistry from the University of Texas-Pan American. Prior to serving in management roles, Dr. Rodriguez established a program in spectroscopic screening techniques using portable Raman and near infrared technologies with an emphasis on using these tools to enhance raw material screening and developing new methods to test finished drugs. Dr. Rodriguez leads a team of scientists that spans a broad cross-section of pharmaceutical research and testing projects including dissolution, chromatography, inhalation, transdermal and mass spectrometry. Dr. Rodriguez is also currently serving as the regulatory chair of the ICH expert working group (Q3E) on development of a guideline on extractables and leachables.

Ilan Geerlof-Vidavsky, Ph.D.
Chemist
Division of Pharmaceutical Analysis (DPA)
OTR | OPQ | CDER

Ph.D. at the Technion – Israel Institute of technology in organic mass spectrometry in 1992. Post-doctoral research at Cornell university 1992-1993 in mass spectrometry. Assistant director at Washington University NIH Mass Spectrometry Resource 1994-2012. Chemist at the FDA Division of Pharmaceutical Analysis in St Louis. 2012-now. LC and MS expert. Coordinator of the Therapeutic Peptide WG in OPQ/OTR

Cameron Smith, Ph.D.
Supervisory Chemist
Division of Liquid-Based Products (DLBP)
Office of Lifecycle Drug Products (OLDP)
OPQ | CDER

Cameron is a Branch Chief in the Office of Lifecycle Drug Products/Office of Pharmaceutical Quality in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration in Silver Spring, MD. Prior to his Agency tenure, he spent 15 years in the pharmaceutical industry as a medicinal chemist, primarily at Merck Research Laboratories in Rahway, NJ and before that at OSI Pharmaceuticals in Durham, NC. Cameron completed his Ph.D. studies in chemistry at the University of Cambridge in Cambridge, UK and followed this up with postdoctoral studies at the University of Utah in Salt Lake City, UT. He obtained his undergraduate degree at Monash University in Melbourne, Australia.

Alicia Hoover, Ph.D.
Chemist
DPA | OTR | OPQ | CDER

Alicia Hoover is a chemist in the Office of Testing and Research. She earned her Ph.D. in analytical chemistry from Saint Louis University in 2014. Her research has included evaluating complex drug delivery systems such as transdermal products, drug products for enteral feeding tube delivery, and abuse deterrent opioid formulations.

Namrata Trivedi, Ph.D.
Chemist
Division of Immediate and Modified Release
Products III (DIMRPIII)
OLDP | OPQ | CDER

Namrata Trivedi is a quality primary assessor in the Division of Immediate and Modified Release Products. She earned her Bachelor's degree in Pharmacy from Saurashtra University, India and Ph.D. in Pharmaceutical Sciences from the University of Tennessee, Memphis. Prior to joining the FDA, she has worked in the pharmaceutical industry for several years. She joined FDA in 2015 in the Office of Lifecycle Drug Products and has served as quality assessor for Immediate and Modified Release ANDA applications and post approval supplements.

Charudharshini Srinivasan, Ph.D.
Research Scientist, Staff Fellow
Division of Product Quality Research (DPQR)
OTR | OPQ | CDER

Dr. Charudharshini Srinivasan is a Regulatory Research Scientist in the Division of Product Quality Research in the Office of Testing and Research, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research (OPQ/CDER/FDA). She leads multiple research projects in the areas of complex parenteral formulations, risk-based assessment of novel pharmaceutical packaging, and product quality assessment through different imaging modalities. She also contributes to several regulatory product quality assessment reviews and policy development. Currently she serves as the Government Liaison to the USP Expert Committee -Glass Expert Panel (EP) and the USP Medical Devices Joint Subcommittee (JS) for Combination Products. She is the subject matter expert for CDER's Emerging Technology Program at the agency for innovative pharmaceutical packaging design. She has received several awards as a recognition to her contributions towards regulatory research and review within FDA.

Dr. Srinivasan received her Ph.D. in Pharmaceutical Sciences from the University of Connecticut, and Bachelor's and Master's degree from India. Prior to joining FDA, she was a Post-Doctoral Associate at MIT and Harvard Medical School.

Yiwei Li, Ph.D.
Supervisory Chemist
Division of Pharmaceutical Manufacturing Assessment III (DPMAIV)
OMPA | OPQ | CDER

Yiwei Li is currently serving as a Branch Chief in the Office of Pharmaceutical Manufacturing Assessment (OPMA) within the Office of Pharmaceutical Quality (OPQ) at the FDA. He supports the assessment of drug product quality and manufacturing processes and facilities for liquid-based dosage forms intended for oral, topical, parenteral and ophthalmic routes. Prior to joining the FDA in 2014, Dr. Li was a research fellow at Merck Research Laboratories and Inception Science. He received his B.Sc. in Chemistry from Peking University (Beijing, China), M. Sc. in Chemistry from University of Guelph (Guelph, Canada), and Ph.D. in Organic Chemistry from The Scripps Research Institute (California, USA). Outside of work, Dr. Li enjoys spending time with family, hiking, and traveling.

Connie Ruzicka, Ph.D.
Lab Chief
DPA | OTR | OPQ | CDER

Dr. Connie Ruzicka is a Laboratory Branch Chief at the Division of Pharmaceutical Analysis (DPA), Office of Testing and Research, Office of Pharmaceutical Quality in the FDA's Center for Drug Evaluation and Research. She received a B.A. in Chemistry from Wayne State University in 1998 and PhD in Analytical Chemistry in 2005 from Missouri University of Science and Technology, formerly known as the University of Missouri – Rolla. After graduation, she began her career at DPA where she worked as an analytical chemist for over 10 years developing methods and utilizing a variety of instrumentation to study the authentication and quality of pharmaceutical products. Dr. Ruzicka was a founding member of DPA's Rapid Spectroscopic Screening team and became a research chemist utilizing rapid screening technologies to assess problems in regulatory pharmaceutical analysis, in particular, the application of ion mobility spectrometry and Raman spectroscopy for the quality assessment of pharmaceutical products and dietary supplements. In 2017, Dr. Ruzicka was promoted to Supervisory Chemist where she plans, directs and manages the work of laboratory personnel performing testing and modern research that promotes the use of advanced techniques to characterize drug products.

Neil Stiber, Ph.D.
Associate Director for Science and Communication
OQS | OPQ | CDER

Neil Stiber is the Associate Director for Science and Communication in the U.S. FDA's Center for Drug Evaluation and Research/Office of Pharmaceutical Quality/Office of Quality Surveillance. During eight years at CDER, he has innovated risk-based approaches, provided collaborative program leadership, and engaged stakeholders to advance pharmaceutical quality. Previously, he was the Director of the Risk Management Staff in the FDA's Office of Regulatory Affairs and for eight years was an environmental scientist at the U.S. EPA. Prior to joining the federal government, he specialized in environmental site investigation and risk assessment. Dr. Stiber earned civil engineering degrees from Duke University and Northwestern University and a Ph.D. from the Department of Engineering and Public Policy at Carnegie Mellon University.

Sau "Larry" Lee
Deputy Director of Science
OPQ | CDER

Dr. Lee directs the activities of staff members in OPQ sub-offices
responsible for the quality assessment of regulatory submissions (OBP, OLDP, ONDP and OPMA). He represents OPQ in programs and activities that impact quality assessments by coordinating with OPQ, CDER, and ORA. He also serves as the point person for the pharmaceutical industry and scientific/academic groups in developing programs to support science- and risk-based application assessment and approval. Dr. Lee has been with the FDA since 2005, serving as a regulatory scientist, team lead, Associate Director for Science, Deputy Office Director, and Office Director. He has provided exemplary leadership in developing OPQ science, research and testing programs to support quality assessment, inspection, surveillance and policy. In 2016, Dr. Lee was appointed to the Senior Biomedical Research Service (SBRS) because of his extensive regulatory and scientific contributions to manufacturing science, complex drug substances and products, and emerging pharmaceutical technologies. Prior to joining the FDA, Dr. Lee received a B.S. degree in Chemical Engineering from the University of Virginia with a minor in Materials Science and a Ph.D. in Chemical Engineering from Princeton University.

Adam Fisher, Ph.D.
Acting Associate Director of Science and Outreach
OPQ | CDER

Adam Fisher, Ph.D. is the Associate Director of Science and Outreach (Acting) in the Immediate Office of the Office of Pharmaceutical Quality (OPQ) in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. In this position, Dr. Fisher focuses on engaging FDA stakeholders and supporting advanced manufacturing technologies. He previously served as a Team Lead on OPQ's Science and Research Staff and focused on research and assessment of complex drug substances and manufacturing processes. He joined the FDA in 2014 as a chemical engineer with expertise in the synthesis of biomolecules. Dr. Fisher's work prior to joining the FDA focused on the microbial production of proteins and glycoproteins for a host of applications. His Ph.D. dissertation concentrated on the use of the secretion pathways of bacteria to perform protein engineering and for this he received the Austin O. Hooey Award for Research Excellence. Prior to the FDA, Dr. Fisher was the co-founder and Chief Science Officer of a startup company focused on microbial technologies for the production of glycoproteins. Here he was awarded several million dollars of research grants as Principal Investigator. Dr. Fisher is the inventor of five patented technologies and the author of over thirty scientific publications and two book chapters. He earned his B.S. degree at the University of Maryland College Park (Chemical Engineering) and his Ph.D. at Cornell University (Chemical & Biomolecular Engineering).

Thomas O'Connor, Ph.D.
Division Director
Division of Product Quality Research
OTR | OPQ | CDER

Dr. O'Connor is the director of the Division of Product Quality Research in the Office of Testing and Research in the Office of Pharmaceutical Quality and is a member of CDER's Emerging Technology Team (ETT). His responsibilities include managing research and testing projects that answer and anticipate pharmaceutical quality-related regulatory challenges through scientific approaches. The impact of OTR research and testing is utilized to support regulatory assessment and policy development in areas such advanced manufacturing, drug quality standards, characterization of complex drug substances and drug products, and post market product quality and public health issues. Tom is a co-author of several papers on emerging pharmaceutical technology (such as continuous manufacturing, 3D printing, and the utilization of modeling and simulation for quality assurance). Through the ETT he has contributed to the review of several regulatory applications utilizing novel technologies. He is the co-chair of the OPQ Manufacturing Science and Innovation Center of Excellence and is a member of the advanced manufacturing working groups within the FDA.

Tom originally joined the FDA as chemistry reviewer in the Office Generic Drugs and prior to joining the FDA, Tom worked at ExxonMobil Research and Engineering where he held job functions in both process analytical technology and process control. Dr. O'Connor earned a B.S. in chemical engineering from the Cooper Union and a Ph.D. in chemical engineering from Princeton University.

Ernest "Ernie" Penachio
Vice President of Technical Operations
CONTINUUS Pharmaceuticals

Ernest Penachio is the Vice President of Operations at CONTINUUS Pharmaceuticals, and is responsible for formulation, process and analytical development, technical operations, engineering, facilities, IT, and MS&T.

Prior to CONTINUUS, Mr. Penachio was the Vice President of Manufacturing Operations and CMC at AZTherapies with accountability for the technology transfer and commercialization of AZT-301, a drug device combination experimental product candidate for the treatment of Alzheimer's disease. Prior to AZTherapies, Ernest was at Acorda Therapeutics, where he was responsible for developing the supply chain and logistics commercialization strategy for the launch of Inbrija™ (levodopa inhalation powder) as well as the Site Head overseeing day-to-day operations at the Chelsea (Massachusetts) manufacturing plant. He also supported the CMC content development for U.S. and EU regulatory submissions. Prior to Acorda, Mr. Penachio was the Director of Manufacturing Operations & Facilities at Civitas Therapeutics, where he was responsible for technical operations and strategic direction for the early- and late-stage CMC development of their pulmonary L-dopa candidate, which was eventually acquired by Acorda in 2014. Ernest was engaged in that project from inception through licensing. Prior to Civitas, Mr. Penachio was at Advanced Inhalation Research (acquired by Alkermes), where he spent ten years working in process development, technology transfer and scale-up, and project management. He led teams responsible for engineering, operations, facilities, process automation, validation, and quality assurance as a Capital Projects Manager/Lead Engineer.
Ernest has also worked as an independent consultant, providing services to clients including Genzyme, Bristol Myers Squibb, Biogen IDEC, and Siemens Healthcare Diagnostics. His areas of expertise include: quality assurance, manufacturing plant setup and operations, and development and management of global commercial supply chains. Ernest is the author of twelve issued patents related to the production of dry particles, creation and filling of capsules and containers, and an inhalation device. Mr. Penachio holds a Bachelor of Science degree in Chemical Engineering from the University of New Hampshire.

John Lewin, PharmD, MBA
Chief Medical Officer
On Demand Pharmaceuticals, Inc.

Dr. Lewin is the Chief Medical Officer of On Demand Pharmaceuticals (ODP) where he oversees the quality and regulatory functions and is developing ODPs current and future manufacturing operations. ODP is an innovative company transforming how medicines are made and supplied to enable a fully automated, end-to-end, deployable, responsive, on-demand capability that does not exist anywhere in the world today. Working with ODP team members, he helps set the research & development strategy with the goal of assuring end user and patient value.
Dr. Lewin is also an associate professor of anesthesiology& critical care medicine at the Johns Hopkins University School of Medicine and maintains a part-time clinical practice in the neurosciences critical care unit at The Johns Hopkins Hospital. Prior to joining ODP full-time, Dr. Lewin was the director of the critical care & Surgery pharmacy division at Johns Hopkins for 11 years.

Dr. Lewin earned his PharmD degree from the Temple University School of Pharmacy, his MBA from the Johns Hopkins University Carey School of Business and completed a PGY1 and PGY2 critical care residency at the Medical University of South Carolina. He has over 19 years of critical care pharmacy experience, with a primary focus on neurological critical care, and is a board-certified critical care pharmacy specialist. He is an author on over 55 peer-reviewed scientific articles and book chapters, and has delivered over 75 invited presentations at local, national, or international conferences. He is a past-president of the Maryland Society of Health-System Pharmacists and has been recognized as a Fellow of the American Society of Health-System Pharmacists, the American College of Critical Care Medicine and the Neurocritical Care Society.